Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, D.C. 20554

In the Matter of

Amendment of § 18.121 of the Commission's Rules to Exempt Non-Consumer Magnetic Resonance Diagnostic Systems from the Technical Standards and the Reporting Requirements of the Commission's Rules	)	RM No. 7903

To: The Commission

COMMENTS OF
HEWLETT-PACKARD COMPANY
MEDICAL PRODUCTS GROUP

Hewlett-Packard Company Medical Products Group ("HP") hereby responds to the Petition for Rulemaking ("Petition") filed by the Magnetic Resonance Section of the National Electrical Manufacturers Association ("NEMA") on January 29, 1992.[1]

HP generally supports initiatives designed to eliminate the burden of unnecessary regulation. With regard to the relief sought by NEMA, there is much that favors the proposition that all reasonable steps should be taken to reduce the regulatory costs imposed on vital medical technologies such as magnetic resonance imaging ("MRI") devices. The Commission should move with great caution in this matter, however, because, contrary to the suggestion made in NEMA's Petition, at 12-13, it is not clear

[1] Pursuant to a Public Notice, Report No. 1877, released February 20, 1992, comments on the Petition are due March 23, 1992.

that MRI devices have not been responsible for causing interference to licensed services, specifically, biomedical telemetry systems operating under Part 90 of the Commission's Rules. As will be discussed in greater detail below, a far more extensive record must be developed before favorable action on NEMA's proposal would be appropriate.

I. HP'S INTEREST IN THE PROCEEDING.

Since 1973, HP has pioneered the development of a variety of new medical technologies for use by hospitals, including a miniaturized electrocardiogram ("ECG") telemetry system that enables the hospital staff continuously to monitor ambulatory heart patients' vital signs, while still permitting those patients the relative freedom to move about in a limited area. An ECG represents the electrical current that stimulates the contraction of the heart muscle and is measured on the skin by wires connected to one or more transducing electrodes. In general, each physiological digital data stream needs 25 kHz of baseband bandwidth in order to ensure error-free transmission. Because clinical problems are identified through distortions in the ECG current, the preferred medical practice is to employ multiple-view, rather than single-view, ECGs, which, of course, increases the per-patient bandwidth requirements.[2] Additionally, doctors need to monitor other vital signs, such as temperature, blood gas and blood pressure, at the same time that they are

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[2] A "view" represents a measurement of the electrical current across the heart, as read from a particular angle to the heart.

monitoring the ECG. Thus, the medical community has growing requirements for more sophisticated monitoring devices that will provide continuous, real-time telemetry covering a broad spectrum of data.

HP's monitors (as well as those of several other companies) operate on the "offset" or "splinter" channels in the 450-470 MHz band, consistent with Section 90.217 of the Rules, 47 C.F.R. § 90.217. The monitoring system consists of three basic components: (1) a small, battery-powered transmitter with 2.0 milliwatt output power (which produces a field strength of up to 50,000 microvolts-per-meter at 3 meters) that is carried by the cardiac patient; (2) a sensitive receiver that is located at a nurses station; and (3) a distributed active antenna system installed in the hallway ceiling of the appropriate hospital wing. The distributed antenna system is designed to ensure that the large number of monitors that must coexist in a limited area are always within 100 feet of an antenna. The 2 mW output power of the units permits HP generally to reuse frequencies at a 5,000 foot separation; in certain cases, depending on building penetration, terrain shielding and like variables, this minimal separation distance can be reduced even further.

The operating requirements of medical monitoring technologies are relatively inflexible. The transmissions must co-exist in close proximity to each other, and be instantaneous, error-free and continuous. The equipment must be extremely portable, so that it may be carried easily by patients, and be capable of low-power transmission for reasons of battery life and

patient safety. Finally, and of increasing importance at a time of rising health care costs, the system must be relatively inexpensive and have direct and demonstrable cost efficiencies and benefits for the medical community.

Since 1973, over 60,000 of HP's ECG monitors have been deployed in over 3,000 hospitals, employing over 250 different channels in the 450-470 MHz band. At some large medical centers, over 200 telemetry channels may be in continuous operation at any given time. The growth in the use of radio-based medical telemetry devices has been substantial, because they provide the medical profession with a vital tool for patient treatment in a cost-effective manner, allowing doctors to take advantage of preferred treatment regimes, which get patients on their feet as soon as possible, without losing any of the essential physiological information necessary for treatment. Thus, use of this technology reduces the costs of improved health care by allowing hospitals to employ fewer medical personnel to monitor patients and by shortening hospital stays. This development has occurred, moreover, at a time when other medical costs have increased substantially and despite a severe shortage of radio frequencies.

II. CONCERNS REGARDING INTERFERENCE TO ECG MONITORING SYSTEMS FROM MRI DEVICES.

Given the necessarily sensitive nature of an ECG monitoring system's receiving antenna, great care must be taken to coordinate these systems with the many RF radiation sources generally present both within and outside a given hospital. As

with the installation and operation of a MRI device, see Petition at 10-12, any number of variables can come into play, depending upon the specific circumstances present in a particular locale. In several instances in the past, HP installation and maintenance personnel have strongly suspected that MRI devices were responsible for intermittent episodes of interference to ECG monitoring systems. Various techniques successfully were employed to eliminate the problem, without the need to attack the source of the interference.

Under the circumstances, far more study of the hospital RF environment should be required before the MRI industry is relieved of its obligation to demonstrate its capacity to meet the relevant emission standards. Indeed, it should be noted that in the Commission's decision to relax the regulation of nonconsumer ultrasonic ISM equipment -- a proceeding heavily relied on by NEMA in its Petition, and one in which HP participated extensively, see Amendment of Part 18, 1 FCC Rcd 553, 554 n.3 (1986) -- the proposal to eliminate the regulations there at issue "was made after undertaking a study on the interference of medical ultrasonic equipment." Id. at 553 & n.4, citing FCC Project Report No. 2226-6. Moreover, as the Commission noted in that decision, the conclusions reached by its initial study were further corroborated by subsequent monitoring conducted by the Field Operations Bureau. Id. at 553. HP

suggests that an equal measure of caution is appropriate in the instant case.[3]

CONCLUSION

Based on the foregoing, HP supports NEMA's Petition to the extent it can be demonstrated that MRI devices will not cause interference to the operation of vital biomedical telemetry systems.

Respectfully submitted,

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[3] It is not an answer to suggest that hospital administrators can be left to resolve these matters. In general, the hospitals rely on the manufacturers of these sophisticated systems (e.g., ECG monitors, MRI devices, ultrasonic diagnostic equipment) to provide essentially turnkey installation; the hospitals have no independent technical capability (or inclination) to become involved in the process of identifying and resolving instances of interference among highly sophisticated systems.

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing Comments of Hewlett-Packard Company Medical Products Group was sent on this 23rd day of March, 1992, by first class United States mail, postage prepaid, to each of the following:

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